Advanced Tools and Technologies for Deep Brain Stimulation

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The official link for this solicitation is: http://grants.nih.gov/grants/guide/pa-files/PA-10-176.html

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Description:

1. Research Objectives

The clinical utility of deep brain stimulation (DBS) for the treatment of the debilitating symptoms of motor disorders, including Parkinson's disease and essential tremor has been established. In addition, DBS may offer relief of symptoms in other disorders such as Dystonia, Tourette's Syndrome and Epilepsy. DBS is considered a treatment option for patients whose symptoms cannot be adequately controlled with medications.

DBS relies on a surgically implanted, battery-operated stimulator to deliver electrical pulses via an implanted multi-contact electrode to targeted areas in the brain that are involved with the control of movement or cognitive function. While the exact mechanism by which high frequency electrical stimulation provided by DBS alters neural circuitry to reduce the burden of disease is unclear, it is evident that for the majority of patients who undergo the procedure, substantial improvements in symptom severity result.

In spite of its clinical success, DBS technology and the associated surgical procedure have several limitations. For example, clinicians lack tools that combine anatomical, physiological, electrical, and behavioral data to optimize electrode placement and stimulator programming. Patients endure significant discomfort during implantation due to the use of rigidly fixed stereotactic frames. In addition, the DBS technology itself is relatively simplistic. The pulse stimulator operates in an always

on, open-loop mode regardless of the severity of patient symptoms and the electrode itself consists of a cylindrical shaft of only a few contacts thus limiting the selectivity of the electrical stimulation. While enhancing some types of motor function, DBS has been less successful in improving other functions, particularly speech. When improvements in speech outcomes after DBS were noted, they were typically minimal and more variable than seen in akinesia, rigidity and dyskinesias. Therefore, there are excellent opportunities for innovation towards improved DBS technology and procedures.

This initiative is intended to stimulate the development of: 1) tools that will facilitate the DBS surgical process, programming, and outcome assessments, and 2) technological innovation in the design of electrode and pulse stimulators. The tools and technology produced by this program will permit enhanced targeting and delivery of therapeutic stimulation in the brain, ultimately improving the quality of life for DBS patients. Useful tools and technology that would be developed in this program will be expected to improve the patients experience during pre-surgical evaluation, surgical procedure, and/or post-surgical follow-up. Also included are technologies that will improve patient outcome and/or reduce unwanted side-effects, such as those related to speech dysfunction. When appropriate, outcomes measures should include assessment of both motor and communication skills. While projects that have the potential for near term clinical impact are strongly encouraged, projects that have an immediate goal of developing research tools for DBS investigations are also permitted. Proposals to explore novel clinical indications for DBS or to perform clinical trials examining safety and/or efficacy of DBS are not appropriate topics for this initiative.

The following objectives would make appropriate topics for proposed Phase I or Phase II projects. This list is not meant to be all-inclusive:

- Intra-operative data analyses and visualization tools that incorporate electrophysiology recordings, imaging data, and brain atlas information to facilitate surgical navigation.
- DBS stimulation parameter software tools that incorporate anatomical, electrical, and physiological data and modeling.
- New imaging technology or multi-modal imaging for enhanced precision in DBS electrode placement.
- Technology allowing frameless DBS surgery during real time imaging.
- Advances to implantable pulse generator technology including, but not limited to: miniaturization, rechargeable/alternative power sources to improve battery lifespan, alternative pulse parameters, and feedback capability to allow closed loop control.
- Advances in DBS electrode technology including, but not limited to: enhanced stimulation selectivity, novel architectures tailored for one or more brain regions, and alternative materials that are compatible with high resolution imaging.
- Novel multi-electrode array technology that enables comprehensive electrophysiological mapping of targeted brain areas.
- Portable diagnostic technology for quantitative assessments of DBS efficacy for relief of motor symptoms or the negative side-effects that have been associated with DBS (e.g., speech dysfunction)

See Section VIII, Other Information - Required Federal Citations, for policies related to this announcement.